K080575

510k Summary

A) Submitted by: INVIA, LCC
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Registration: 9069896

MAY 13 2008

Contact: MEDIcept
200 Homer Ave
Ashland, MA 01721
F. David Rothkopf
508-231-8842 x20
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B) Device Name: Corridor4DM
Common Name: System, Emission Computed Tomography & System, X-Ray Computed Tomography

Device Class: 21 CFR 892.1200
21 CFR 892.1750 CLASS II

Product Code KPS, JAK

C) Predicate:
Reagents of the University of Michigan *3D-MSPECT* system (K001026)
Siemens, Calcium Scoring Software Package (K990426)

D) Device Description:

Corridor4DM is a comprehensive cardiac emission computed tomographic (ECT) application designed to review and quantitatively analyze cardiac ECT (SPECT and PET) nuclear medicine patient studies. The application provides tools for processing and displaying standard ungated and ECG gated cardiac ECT images on both a slice-by-slice basis and as a 3-dimensional surface rendered images in many user selectable formats. Additionally, it provides quantitative assessments of heart function by computing and displaying left ventricular chamber volumes, ejection fraction and transient ischemic dilation (TID) values and provides an assessment of the data set(s) in comparison to a similar patient population with a low likelihood of cardiac disease. The application provides a number of different single or multi-dimensional display(s) to allow the users to select those that best fit their needs. Cardiac CT interpretation and cardiac calcium quantification are optional features that are integrated into Corridor4DM.

E) Intended Use:
Invia's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of reconstructed cardiac emission tomographic studies (SPECT and PET). Cardiac CT interpretation and calcium quantification are optional features that are integrated into Corridor4DM (SPECT-CT and PET-CT). The calcium-scoring package is a non-invasive diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, a risk factor for coronary artery disease. Calcium scoring may be used to monitor the progression or regression overtime of the amount or volume of calcium in the coronary arteries, which may be related to the prognosis of a cardiac attack. Coregistration or fusion of volumetric data (ECT and/or CT) is provided as a quality control for the identification of structures where correlative spatial information is necessary for a diagnostic interpretation.

F) Comparison to Predicate Device(s):
The Corridor 4DM has the same intended use, target population, and clinical setting as other SPECT software including the predicate devices. It uses the same technology as the predicate devices (*3D-MSPECT* system (K001026) and Calcium Scoring Software Package (K990426).

Features	Corridor4DM	3D-MSPECT	Siemens Calcium Scoring Software Package
Computer based templating system	Yes	Yes	NA
Digital image retrieval of patient radiographs	Yes	Yes	NA
Patient Studies Type	ECT, PET, CT	ECT, PET	N/A
Measurement Tools	Yes	Yes	NA
Overlay of prosthetic templates for proper selection by physician	Yes	Yes	NA
Generation of Parts List	Yes	Yes	NA
Patient files can be saved locally, on a network, or printed.	Yes	Yes	NA
Allows for assessment of wear.	Yes	Yes	NA
Identify and quantify CT data via imaging	Yes	No	Yes

G) Guidance Document
Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems; Final, FDA December 3, 1998

H) Conclusion:
Invia, LLC believes that the Corridor4DM is substantially equivalent to the predicate devices based on intended usage, technology comparison and system performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 2008

Invia
Mr. F. David Rothkopf
President
MEDIcept, Inc.
200 Homer Ave
ASHLAND MA 01721

Re: K080575
Trade/Device Name: Corridor4DM
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS, JAK, and LLZ
Dated: February 20, 2008
Received: February 29, 2008

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K080575

Device Name: Corridor4DM

Indications for Use:

Invia's Corridor4DM application is intended to provide processing, quantification, and multidimensional review of reconstructed cardiac emission tomographic studies (SPECT and PET). Cardiac CT interpretation and calcium quantification are optional features that are integrated into Corridor4DM (SPECT-CT and PET-CT). The calcium-scoring package is a non-invasive diagnostic tool that can be used to evaluate the calcified plaques in the coronary arteries, a risk factor for coronary artery disease. Calcium scoring may be used to monitor the progression or regression overtime of the amount or volume of calcium in the coronary arteries, which may be related to the prognosis of a cardiac attack. Coregistration or fusion of volumetric data (ECT and/or CT) is provided as a quality control for the identification of structures where correlative spatial information is necessary for a diagnostic interpretation.

Prescription Use __X__ OR Over-the-Counter Use ___ 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K080575